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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,093	08/24/2001	Graham Nigel Maw	PC10347AGLK	2991

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Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,093	MAW ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application was filed August 24, 2001 and claims priority to U.S. Provisional Application 60/238,206, filed October 5, 2000 and claims priority to foreign application 0021487.4 filed September 1, 2000 in Great Britian.

Claims 1-31 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a pharmaceutical composition for use (or when in use) in the treatment of a sexual dysfunction, classified in class 514, subclass 1+.

II. Claims 7-13, drawn to a method of treatment comprising administering to a subject an agent capable of modulating an IK_{Ca} channel activity in the sexual genitalia, classified in class 514, subclass 1+.

III. Claims 14-22, drawn to an *in vitro* method of identifying an agent capable of modulating an IK_{Ca} channel activity in order to treat an SD, an agent identified by this method, and a method of treating an SD with the identified agent, classified in class 514, subclass 1+.

IV. Claim 23 and 24, drawn to a diagnostic method and kit wherein the method comprises: isolating a sample from the sexual genitalia of an individual; determining whether the expression and/or IK_{Ca} channel activity in the sample from the individual has an effect on the relaxation of corpus cavernosal smooth muscle tone, classified in class 536, subclass 23.1, or class 530, subclass 350+.

V. Claims 25 and 26, drawn to an animal model useful in the identification of agents capable of treating SD and a method of identifying an agent capable of modulating IK_{Ca} channel activity in order to treat an SD (preferably MED); the assay method comprising: administering an agent to the animal model and measuring the IK_{Ca} channel open time probability in the sexual genitalia, classified in class 800, subclass 3.

VI. Claims 27-29, drawn to a method of identifying agents capable of mediating the relaxation of corpus cavernoal smooth muscle tone comprising using an IK_{Ca} channel as a target, classified in class 514, subclass 1+.

VII. Claims 30-31, drawn to an $\underline{IK_{Ca}\ channel}$ used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone, classified in class 530, subclass 350+.

VIII. Claims 30-31, drawn to <u>an agent</u> used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone, classified in class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case Invention I can be used in modulating the activity of an IK_{Ca} channel in other organs or tissues.

Inventions I/II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I/II are to a pharmaceutical composition and method of treatment comprising administering the pharmaceutical composition. Invention III is to *in vitro* methods of identifying an agent and treating SD, and to the agent. Inventions I/II encompasses *in vivo* use, which is materially and methodically different from Invention I.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention VII is an IK_{Ca} channel used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone. Invention VIII is an agent used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone. Invention VII does not depend on Invention VIII to function and vice versa.

Inventions I/II/III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I, II, III are to a pharmaceutical, and methods of using and

identifying pharmaceutical in the treatment of SD. Invention IV is to diagnostic method wherein the method comprises: isolating a sample from the sexual genitalia of an individual; determining whether the expression and/or IK_{Ca} channel activity in the sample from the individual has an effect on the relaxation of corpus cavernosal smooth muscle tone. Inventions I/II/III do not depend on Invention IV to function and vice versa.

Inventions I/II/III and V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions I/II/III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I/II/III are to a pharmaceutical, and methods of using and identifying pharmaceutical in the treatment of SD. Invention VI is a method of identifying agents capable of mediating the relaxation of corpus cavernoal smooth muscle tone comprising using an IK_{Ca} channel as a target. Inventions I/II/III do not depend on Invention VI to function and vice versa.

Inventions I/II/III and VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, an IK_{Ca} channel can be found in other tissues other than corpus cavernosal smooth muscle. Further, an agent used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle is not limited to mediation via the IK_{Ca} channel.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention IV is to a diagnostic method and kit wherein the method comprises: isolating a sample from the sexual genitalia of an individual; determining whether the expression and/or IK_{Ca} channel activity in the sample from the individual has an effect on the relaxation of corpus cavernosal smooth muscle tone. Invention V is an animal model useful in the identification of agents capable of treating SD and a method of identifying an agent capable of modulating IK_{Ca} channel activity in order to treat an SD (preferably MED); the assay method comprising: administering an agent to the animal model and measuring the IK_{Ca} channel open time probability in the sexual genitalia. Invention IV does not depend on Invention V to function and vice versa.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention IV is to a diagnostic method and kit wherein the method comprises: isolating a sample from the sexual genitalia of an individual; determining whether the expression and/or IK_{Ca} channel activity in the sample from the individual

has an effect on the relaxation of corpus cavernosal smooth muscle tone. Invention VI is a method of identifying agents capable of mediating the relaxation of corpus cavernoal smooth muscle tone comprising using an IK_{Ca} channel as a target. Invention IV does not depend on Invention VI to function and vice versa.

Inventions IV and VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention IV is a diagnostic method and kit wherein the method comprises: isolating a sample from the sexual genitalia of an individual; determining whether the expression and/or IK_{Ca} channel activity in the sample from the individual has an effect on the relaxation of corpus cavernosal smooth muscle tone. Invention VII/VIII is an IK_{Ca} channel or an agent used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone. Invention IV does not depend on Inventions VII/VIII to function and vice versa.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention V is an animal model useful in the identification of agents capable of treating SD and a method of identifying an agent capable of modulating IK_{Ca} channel activity in order to treat an SD (preferably MED); the assay method comprising: administering an agent to the animal model and measuring the IK_{Ca} channel open time probability in the sexual genitalia. Invention VI is a method of identifying agents capable

of mediating the relaxation of corpus cavernoal smooth muscle tone comprising using an IK_{Ca} channel as a target. Invention V does not depend on Invention VI to function and vice versa.

Inventions V and VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V is an animal model useful in the identification of agents capable of treating SD and a method of identifying an agent capable of modulating IK_{Ca} channel activity in order to treat an SD (preferably MED); the assay method comprising: administering an agent to the animal model and measuring the IK_{Ca} channel open time probability in the sexual genitalia. Invention VII/VIII is an IK_{Ca} channel or an agent used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth muscle tone. Invention IV does not depend on Inventions VII/VIII to function and vice versa. Invention V does not depend on Invention VII/VIII to function and vice versa.

Inventions VI and VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention VI is a method of identifying agents capable of mediating the relaxation of corpus cavernoal smooth muscle tone comprising using an IK_{Ca} channel as a target. Invention VII/VIII is an IK_{Ca} channel or an agent used in enhancing nitregic or nitric oxide-mediated relaxation of corpus cavernosal smooth

muscle tone. Invention VI does not depend on Invention VII/VIII to function and vice versa.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and that the search for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

Joe Woitach
AU1632